

**FEE TRANSMITTAL**  
FY 2006

JUL 05 2007  
PATENT OFFICE

Complete if Known

Application Serial Number	10/775,169
Filing Date	February 11, 2004
First Named Inventor	Burczynski
Group Art Unit	1636
Examiner Name	Schlapkohl, Walter
Attorney Docket No.	WYE-024

## METHOD OF PAYMENT

1. ☐ Payment Enclosed:  
☐ Check ☐ Money Order ☐ Other

2. ☒ The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 50-1721.

- ☒ Required Fees (copy of this sheet enclosed).  
☒ Additional fee required under 37 CFR 1.16 and 1.17.  
☒ Overpayment Credit.

3. ☐ Applicant claims small entity status.

## FEE CALCULATION

## 1. FILING/SEARCH/EXAM/SIZE FEES

## Large Entity

Fee (\$)	Fee Description	Fee Paid
300	Utility filing fee	
500	Utility search fee	
200	Utility exam fee	
250	Utility size fee (each add'l 50 pgs. over 100)	
200	Design filing fee	
100	Design search fee	
130	Design exam fee	
250	Design size fee (each add'l 50 pgs. over 100)	

	Number Filed	Number Extra	Rate	Amount
Total Claims	- 20 =		x \$ 50.00 =	

Independent Claims	- 3 =		x \$200.00 =	
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☐ Multiple Dependent Claim(s), if any \$360.00 =

TOTAL:  
SMALL ENTITY DISCOUNT:

SUBTOTAL (1) (\$) 0.00

## 2. AMENDMENT CLAIM FEES

Claims	Highest No. Remained After Amend.	Present Previously Paid For	Rate	Fee Paid
Total	-	=	x \$ 50.00 =	
Indep.	-	=	x \$200.00 =	

☐ First Presentation of Multiple Dep. Claim + \$360.00 =

TOTAL: (\$)  
SMALL ENTITY DISCOUNT: (\$)

SUBTOTAL (2) (\$) 0.00

## FEE CALCULATION (continued)

## 3. ADDITIONAL FEES

Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid
130	65	Surcharge - late filing fee or oath	
50	25	Surcharge - late provisional filing fee or cover sheet	
130	130	Non-English specification	
2,520	2,520	Request for ex parte reexamination	
120	60	Extension for reply within first month	
450	225	Extension for reply within second month	
1020	510	Extension for reply within third month	
1590	795	Extension for reply within fourth month	
2160	1080	Extension for reply within fifth month	
500	250	Notice of Appeal	
500	250	Filing a brief in support of an appeal	
1000	500	Request for oral hearing	
400	400	Petitions to the Commissioner (Gp. I)	
200	200	Petitions to the Commissioner (Gp. II)	
130	130	Petitions to the Commissioner (Gp. III)	
180	180	Submission of Information Disclosure Statement	180.00
790	395	Filing a submission after final rejection (37 CFR 1.129(a))	
790	395	For each additional invention to be examined (37 CFR 1.129(b))	
100	100	Certificate of Correction for applicant's error	
130	65	Submission of Terminal Disclaimer	
Other fee (Specify)			
Other fee (Specify)			

SUBTOTAL (3) (\$) 180.00

SUBTOTAL (1) 0.00

SUBTOTAL (2) 0.00

SUBTOTAL (3) 180.00

TOTAL (\$) 180.00

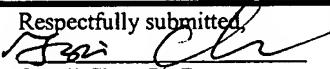
## CORRESPONDENCE ADDRESS

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Gates Ellis LLP  
State Street Financial Center  
One Lincoln Street  
Boston, MA 02111-2950  
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## SIGNATURE BLOCK

Date: July 5, 2007  
Reg. No.: 51,551  
Tel. No.: (617) 261-3198  
Fax No.: (617) 261-3175

Respectfully submitted,  
  
Fangli Chen, Ph.D.  
Attorney for the Applicants  
Kirkpatrick & Lockhart Preston  
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One Lincoln Street  
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07-09-07

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*[Handwritten signature]*

PATENT  
Attorney Docket No. WYE-024

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Burczynski *et al.*  
SERIAL NO.: 10/775,169 GROUP NO.: 1636  
FILING DATE: February 11, 2004 EXAMINER: Schlapkohl, Walter  
TITLE: Methods for Monitoring Drug Activities in Vivo

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the non-patent publications are enclosed.

REMARKS

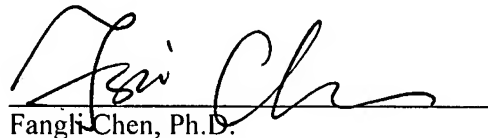
In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) above but before the mailing of a **first Office action** under 37 C.F.R. 1.113, a **notice of allowance** under 37 C.F.R. 1.311, or an action that otherwise closes prosecution in the application, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein; or

- ☐ (3) after the period defined in (2) above but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the foreign patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

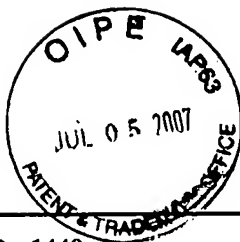
Respectfully submitted,



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Boston, Massachusetts 02111-2950

Date: July 5, 2007  
Reg. No. 51,551

Tel. No.: (617) 261-3198  
Fax No.: (617) 261-3175



<b>FORM PTO - 1449</b> <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>	<b>ATTORNEY DOCKET NO.:</b> WYE-024 <b>APPLICANT(S):</b> Burczynski <i>et al.</i> <b>SERIAL NO.:</b> 10/775,169 <b>FILING DATE:</b> February 11, 2004 <b>GROUP NO.:</b> 1636
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**U.S. PATENT DOCUMENTS**

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	2004/0018528	01/29/2004	Morimoto <i>et al.</i>			

**OTHER ART, JOURNAL ARTICLES, ETC.**

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	CA	Bae <i>et al.</i> *(2000), "The Detection of Circulating Breast Cancer Cells in Peripheral Blood by Reverse Transcriptase-Polymerase Chain Reaction," <u>J. Korean Med Sci</u> , 15:194-198.
	CB	Results of Blast, (2006), <a href="http://www.ncbi.nlm.nih.gov/blast/Blast.cgi">http://www.ncbi.nlm.nih.gov/blast/Blast.cgi</a> , p. 1-16.
	CC	Cao <i>et al.</i> , (1994), "Human Gastric Adenocarcinoma Cathepsin B: Isolation and Sequencing of Full-Length cDNAs and Polymorphisms of the Gene," <u>Gene</u> , 1 pg-abstract only.
	CD	Deprimo <i>et al.</i> , (2003), "Expression Profiling of Blood Samples from an SU5416 Phase III Metastatic Colorectal Cancer Clinical Trial: a Novel Strategy for Biomarker Identification," <u>Biomed Central</u> , 1-16.
	CE	Enard <i>et al.</i> , (2002), "Intra- and Interspecific Variation in Primate Gene Expression Patterns," <u>Science</u> , p. 340-343.
	CF	GenBank, (1999), Locus: HUMCYCLORA, Accession: L04288, p. 1-4.
	CG	Hidalgo <i>et al.</i> , (2000), "The Rapamycin-Sensitive Transduction Pathway as a Target for Cancer Therapy," <u>Oncogene</u> , 19:6680-6686.
	CH	Hill <i>et al.</i> , (2001), "Evaluation of Normalization Procedures for Oligonucleotide Array Data Based on Spiked cRNA Controls," <u>Genome Biology</u> , 2(12):research0055.1-0055.13.
	CI	Kaempfer <i>et al.</i> , (1996), "Prediction of Response to Treatment in Superficial Bladder Carcinoma Through Pattern of Interleukin-2 Gene Expression," <u>J. Clin. Oncol.</u> , 14:1778-1786.
	CJ	Liu <i>et al.</i> , (2001), "Upregulation of Toll-Like Receptor 2 Gene Expression in Macrophage Response to Peptidoglycan and High Concentration of Lipopolysaccharide Is Involved in NF- $\kappa$ B Activation," <u>Infection and Immun.</u> , 69:2788-2796.
	CK	Olive <i>et al.</i> , (1998), "Expression of Cytokine mRNA Transcripts in Renal Cell Carcinoma," <u>Immun. And Cell Biol.</u> , 76:357-362.
	CL	Panelli <i>et al.</i> , (2002), "Gene-Expression Profiling of the Response of Peripheral Blood Mononuclear Cells and Melanoma Metastases to Systematic IL-2 Administration," <u>Genome Biology</u> , 3(7):research0035.1-0035.17.

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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<b>FORM PTO - 1449</b> <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>		ATTORNEY DOCKET NO.: WYE-024 APPLICANT(S): Burczynski <i>et al.</i> SERIAL NO.: 10/775,169 FILING DATE: February 11, 2004 GROUP NO.: 1636
	CM	Park <i>et al.</i> , (2002), "Identification of Radiation-Specific Responses From Gene Expression Profile," <u>Oncogene</u> , 21:5421-8528.
	CN	Thisted, (1998), "What Is A P-Value?" <a href="http://www.stat.uchicago.edu/~thisted">www.stat.uchicago.edu/~thisted</a> , p. 1-6.
	CO	Van 't Veer <i>et al.</i> , (2002), "Gene Expression Profiling Predicts Clinical Outcome of Breast Cancer," <u>Nature</u> , 415:530-536.
	CP	Yeang <i>et al.</i> , (2001), "Molecular Classification of Multiple Tumor Types," <u>Bioinformatics</u> , 17:Suppl. S316-S322.
	CQ	Zwicky <i>et al.</i> , (2002), "Cathepsin B Expression and Down-Regulation by Gene Silencing and Antisense DNA in Human Chondrocytes," <u>Biochem J.</u> , 367:209-217.
	CR	PCT International Search Report for International Application No.: PCT/US04/004118 (Date of mailing 1/19/2005).
	CS	PCT International Search Report for International Application No.: PCT/US04/013587 (Date of mailing 1/25/2005).
	CT	PCT International Search Report for International Application No.: PCT/US06/005772 (Date of mailing 8/11/2006).

EXAMINER	DATE CONSIDERED
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